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# NOTICE OF ALLOWANCE AND FEE(S) DUE

23599 7590 06/09/2009

MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD.

SUITE 1400 ARLINGTON, VA 22201 EXAMINER BIANCHI, KRISTIN A

ART UNIT PAPER NUMBER

1626 DATE MAILED: 06/09/2009

 APPELICATION NO.
 FILING DATE
 FIRST NAMED INVENTOR
 ATTORNEY DOCKET NO.
 CONTRIBATION NO.

 10/679/825
 05/17/2006
 Dirk Finninger
 MERCK-3165
 5742

 TITLE OF INVENTION: PYRKOLE DERIVATIVES
 5742
 THE PROPERTY OF THE PROPERTY

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	09/09/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FIEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

## PART B - FEE(S) TRANSMITTAL

# Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This appropriate. All further c indicated unless correcte maintenance fee notificat	form should be used for correspondence including d below or directed oth ions.	or tran g the l erwise	smitting the ISSU Patent, advance or in Block 1, by (a	TE FEE and PUBLIC ders and notification specifying a new of						
CURRENT CORRESPONDENCE ADDRESS (Noze: Use Block 1 for any change of address)				Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.						
23599 7590 060902009 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 14400						Cer	tificate	of Mailing or Trans s) Transmittal is being ficient postage for firs ISSUE FEE address I) 273-2885, on the di	nission deposited with the class mail in an a above, or being to the indicated below	e United envelope facsimile
ARLINGTON, V	'A 22201								(Deposit	tor's name)
									(	(Signature)
					L					(Date)
APPLICATION NO.	FILING DATE			FIRST NAMED INVEN	TOR		ATTO	RNEY DOCKET NO.	CONFIRMATION	NO.
10/579,825	05/17/2006			Dirk Finsinger			1	MERCK-3165	5742	
TITLE OF INVENTION:	PYRROLE DERIVAT	IVES								
APPLN. TYPE	SMALL ENTITY	IS:	SUE FEE DUE	PUBLICATION FEE I	DUE	PREV. PAID ISSU	SFEE	TOTAL FEE(S) DUE	DATE DU	
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EXAMI	NER		ART UNIT	CLASS-SUBCLAS	S	J				
BIANCHI, K			1626	514-343000						
1. Change of correspondence address or indication of "Fee Address" (3 CFR 1.861).  Change of correspondence address (or Change of Correspondence Address form PTOSB/122) attached.  "Fee Address" indication (or "Fee Address" Indication form PTOSB/12; Nev 03-02 or more recent) attached. Use of a Custom Number is required.			Correspondence	2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a 2 registered patent attorneys or agents. If no name is listed, no name will be printed.						
3. ASSIGNEE NAME AN PLEASE NOTE: Unle recordation as set forth (A) NAME OF ASSIG	ess an assignee is ident in 37 CFR 3.II. Comp				the p g an	atent. If an assign assignment. and STATE OR C	OUNT	RY)		
Please check the appropri	ate assignee category or	catego	ries (will not be pr	inted on the patent):		Individual 🚨 Co	rporati	on or other private gro	up entity 🚨 Gov	ernment
4a. The following fee(s) are submitted:    Issue Fee   Publication Fee (No small entity discount permitted)   Advance Order - # of Copies				A check is enclo Payment by cred The Director is h	sed. it car ereby	d. Form PTO-2038	is atta	required fee(s), any det		any s form).
	SMALL ENTITY state	s. See	37 CFR I.27.					ITTY status. Sec 37 CF		
NOTE: The Issue Fee and interest as shown by the re	Publication Fee (if requeered of the United Sta	rired) v tes Pate	will not be accepted ent and Trademark	d from anyone other t Office.	han t	he applicant; a regi	stered.	attorney or agent; or th	e assignee or other	party in
Authorized Signature						Date				
Typed or printed name						Registration N	lo			
This collection of informa an application. Confident submitting the completed this form and/or suggestic Box 1450, Alexandria, Vi Alexandria, Virginia 2231	tion is required by 37 C iality is governed by 35 application form to the ons for reducing this bur rginia 22313-1450. DC 3-1450.	FR 1.3 U.S.C. USPT den, st NOT	11. The informatic 122 and 37 CFR O. Time will vary nould be sent to the SEND FEES OR (	on is required to obtain 1.14. This collection depending upon the Chief Information COMPLETED FORM	n or r is est indiv Office IS TO	retain a benefit by t imated to take 12 i idual case. Any co er, U.S. Patent and D THIS ADDRESS	he pub minuter mmen Trader i. SEN	tic which is to file (and to complete, includin s on the amount of tir nark Office, U.S. Depa D TO: Commissioner i	by the USPTO to g gathering, prepar ne you require to out thent of Comme or Patents, P.O. B	process) ring, and complete rce, P.O. ox 1450,

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DATE MAILED: 06/09/2009

	APPLICATION NO.	FILING DATE FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.	CONFIRMATION NO.	
	10/579,825	05/17/2006 Dirk Finsinger		MERCK-3165	5742	
	23599 75	90 06/09/2009		EXAM	INER	
	MILLEN, WHIT	E, ZELANO & BRA	BIANCHI, KRISTIN A			
2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				ART UNIT	PAPER NUMBER	
				1626		

# Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 465 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 465 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

# Notice of Allowability

Application No.	Applicant(s)
10/579,825	FINSINGER ET AL.
Examiner	Art Unit
KRISTIN BIANCHI	1626

— The MAILING DATE of this communication appears on the cover sheat with the correspondence addressAll claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included
herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS
NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative
of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- This communication is responsive to 03/09/2009.
- 2. The allowed claim(s) is/are 12-14,26,27 and 35-53.
- 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) 

    All b) 

    Some\* c) 

    None of the:
    - 1. A Certified copies of the priority documents have been received.
    - 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
    - Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDOMMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- 5. CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) Thereto or 2) to Paper No./Mail Date
  - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

 DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- 1. Notice of References Cited (PTO-892)
- 2. Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3. Information Disclosure Statements (PTO/SB/08),
- Examiner's Comment Regarding Requirement for Deposi of Biological Material
- 5. Notice of Informal Patent Application
- Interview Summary (PTO-413).
- Paper No./Mail Date <u>05/26/2009</u> .

  7. 

  Examiner's Amendment/Comment
- 9. ☐ Other

Application/Control Number: 10/579,825 Page 2

Art Unit: 1626

# DETAILED ACTION

Claims 12-14, 22-27 and 35-53 are pending in the instant application. Claims 1-11, 15-21 and 28-34 were cancelled and new claims 35-53 were added by way of amendment filed on March 9, 2009. Claims 22-25 are cancelled by way of examiner's amendment. Claims 12-14, 26, 27, and 35-53 are allowed.

## Response to Amendment and Remarks

The amendment and remarks filed on March 9, 2009 have been fully considered and entered into the application. In regards to the 35 U.S.C. 112, first paragraph, rejection of claims 1-14 and 28-34, the grounds for rejection are most in view of Applicant's amendment and the 35 U.S.C. 112, first paragraph, rejection has been withdrawn. In regards to the 35 U.S.C. 103(a) rejection of claims 1-14 and 28-34 over US 2004/0138269, Applicant argues that the mere disclosure of a broad genus does not render obvious each and every embodiment encompassed therein. Applicant also argues that the specific compounds disclosed by Sun et al. do not exhibit a pyridinyl group for B (i.e., B is phenyl) and the group L is always -CO-NH-, -CO-NH-CH2-, -NH-CO-, or -NH-CO-NH-. These arguments have been found to be fully persuasive and the 35 U.S.C. 103(a) rejection has been withdrawn. In regards to the 35 U.S.C. 103(a) rejection of claims 1-3, 6, 7, 11, 14, 28, and 29 over US 2008/0234270, the grounds for rejection are moot in view of Applicant's amendment and also by the submission of the certified English translation of Applicant's German priority application, DE 103 54 060.1. Therefore, the 35 U.S.C. 103(a) rejection has been withdrawn.

## EXAMINER'S AMENDMENT

Art Unit: 1626

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The claims have been amended as follows: claims 22-25 are cancelled.

## REASONS FOR ALLOWANCE

The compounds, pharmaceutical compositions and method of making the compounds of the instant claims are novel and non-obvious over the prior art because of the structural limitations that X is oxygen and Ar is pyridinyl. The closest prior art is US 2004/0138269 which discloses compounds of formulas I-III (i.e., [0020]-[0048]) or specific compounds (i.e., [0049]-[0105]) wherein the B group is phenyl (i.e., not pyridinyl as in the instant claims) and the L group is -CO-NH-, -CO-NH-CH2-, -NH-CO-, or -NH-CO-NH- (i.e., not oxygen as in the instant claims). The compounds disclosed in US 2004/0138269 do not fit within the scope of the compounds of the instant claims nor are they obvious variants. Therefore, the compounds disclosed in US 2004/0138269 have different properties than the compounds of the instant claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

## Conclusion

Art Unit: 1626

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTIN BIANCHI whose telephone number is (571)270-5232. The examiner can normally be reached on Mon-Fri 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kamal A Saeed/ Primary Examiner, Art Unit 1626 Kristin Bianchi Examiner Art Unit 1626

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